OIPE JC173 JUL 11 2005 PATENT & TRADEMARK OFFICE

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Number: 6,863,901

Date Issued: March 8, 2005

Name of Patentees: Jane Hirsh, Kamal Midha, Mark Hirsh, and Whe-Yong Lo

Title of Invention: *PHARMACEUTICAL COMPOSITION FOR COMPRESSED ANNULAR TABLET WITH MOLDED TRITURATE TABLET FOR BOTH INTRAORAL AND ORAL ADMINISTRATION*

ATTN: Certificate of Correction Branch
Commissioner for Patents
P.O Box 1450
Alexandria, VA 22313-1450

Certificate
JUL 14 2005
of Correction

REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT DUE TO PTO'S AND APPLICANTS' ERRORS

Sir:

Attached in duplicate is form PTO/SB/44 with at least one copy being suitable for printing.

In accordance with MPEP 1485, the exact page, and/or claim, and line number where the errors occurred in the application as filed are identified herein.

1. Page 3, line 13
2. Page 4, line 8
3. Page 7, line 15
4. Page 8, line 16
5. Page 10, line 8
6. Page 21, line 7

07/13/2005 AADOF01 00000001 503129 6863901
01 FC:1811 100.00 DA

7. Page 30, line 5
8. Page 41, line 1

5 2005 5 2005

9. Page 42, lines 16 and 19

10. Page 48, line 3

11. Page 53, line 10

12. Page 59, line 3

13. Page 64, line 9

14. Page 70, line 4

15. Claim 1 on page 75, line 7

16. Claim 16, page 79, lines 11-16, as amended and renumbered as claim 15

17. Claim 20, page 81, line 10, as amended and renumbered as claim 19

18. Claim 21 (a), page 81, line 19, as amended and renumbered as claim 20

19. Claim 21 (a), page 81, lines 1-4, as amended and renumbered as claim 20

20. Claim 21 (b)(ii), page 82, lines 10 and 13, as amended and renumbered as claim 20

21. Claim 22, page 82, line 20, as amended and renumbered as claim 21

Applicant's Error

It is noted that errors 1-2, 4-6, 8-14 and 16 listed above are obvious clerical and typographical errors by the Applicant, as more fully described below. These errors are of an. Errors 1, 6 and 16 are misspellings due to typographical errors. In error 1 on page 3, line 13, "clormipramine" should be deleted and replaced with "clomipramine". Clomipramine is the correct spelling for the drug which is sold under the brandname Anafranil (see the enclosed printout from the Food and Drug Administration's On-Line Orange Book, www.accessdata.fda.gov). In error 6 on page 21, line 7, "Kiusui" should be deleted and replaced with "Kikusui" (see the enclosed product description, www.kikusui.com/English/clec.htm). In error 16 in claim 16, page 79, lines 11-16 (renumbered in the patent as claim 15), as amended by

2005

the applicants in the Amendment and Response filed on August 11, 2004, "phentanyl" should be deleted and replaced with "fentanyl" Support for the correct spelling can be found on on page 14, line 12 of the specification as originally filed. The correct spelling of fentanyl is also shown in the enclosed printout from the on-line encyclopedia, Wikopedia (www.wikopedia.com).

Errors 2, 4-5, and 9 are grammatical errors due to typographical errors. In error 2 on page 4, line 8, "powders" should be deleted and replaced with "powder". In error 4 on page 8, line 16, between "pharmaceutical" and "unit", "in" should be deleted, and "is in the form" should be deleted. In error 5 on page 10, line 8, "compounds" should be deleted and replaced with "compound". In error 9 on page 42, "releases" in line 16 should be deleted and replaced with "release" and "provide" in line 19 should be deleted and replaced with "provides".

Error 8 is a typographical error. In error 8 on page 41, line 1, the acronym "CAT" should be deleted and inserted in line 2, after "Zolmitriptan". Support for the correction can be found on page 36, line 8 of the specification as originally filed.

Errors 10-14 involve the use of an incorrect acronym due to typographical errors. In each of these locations, specification should refer to "CAT" which is the acronym for "compressed angular tablet" (see p. 1, lines 13-14 of the specification as originally filed). In error 10 on page 48, line 4, the acronym "CTCC" should be deleted and replaced with the acronym "CAT". Support for the correction can be found on page 43, line 5 of the specification as originally filed. In error 11 on page 53, line 10, and error 12 on page 59, line 3, the acronym "CTCC" should be deleted and replaced with the acronym "CAT". Support for these corrections can be found on page 50, line 7 and page 52, line 7 of the specification as originally filed. In error 13 on page 64, line 9, and error 14 on page 70, line 4, the acronym "CTCC" should be deleted and replaced with the acronym "CAT". Support for these corrections can be found on page 61, lines 8-9 and page

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63, line 12 of the specification as originally filed. These errors occurred in good faith, and correction thereof does not involve such changes in the patent as would constitute new matter or would require reexamination.

PTO Error

Errors 3, 7, 15, and 17-21 occurred due to typographical errors by the United State Patent and Trademark Office. In error 3 on page 7, line 15, "Imanufacturing" should be deleted and replaced with "manufacturing". In error 15 in claim 1, page 75, line 1, "lease" should be deleted and replaced with "least". In error 17 in claim 20, page 81, line 10 (renumbered as claim 19), "step" should be deleted and replaced with "steps". In error 18 in claim 21 (a), page 81, line 19 (renumbered as claim 20), "potion" should be deleted and replaced with "portion". In error 19, in claim 21 (a), page 81, lines 1-4, as amended by the applicants in the Amendment and Response filed on August 11, 2004 (renumbered as claim 20), "has" should be deleted. In error 20 in claim 21, page 82, lines 10 and 13 (renumbered as claim 20), "fit" should be deleted and replaced with "first" and "hereby" should be deleted and replaced with "thereby". In error 21 in claim 22, page 82, line 20 (renumbered as claim 21), "indent" should be deleted and replaced with "ingredient". In error 7 on page 30, line 5, the number "5" should be deleted. Corrections of these errors does not involve such changes in the patent as would constitute new matter or would require reexamination.

Please issue a Certificate of Correction or a corrected patent, if the Commissioner deems that to be more appropriate, and send the document to:

Customer No. 23579
Patrea L. Pabst
Pabst Patent Group, LLP
400 Colony Square, Suite 1200
1201 Peachtree Street
Atlanta, GA 30361

The Commissioner is hereby authorized to charge $100, the fee for a Certificate of Correction due to Applicant's error as required by 37 CFR §1.20(a), to Deposit Account No. 50-3129. Applicants believe that no additional fees are required. However, should an additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

Very truly yours,

PABST PATENT GROUP, LLP

Rivka D. Monheit

Rivka D. Monheit
Reg. No. 48,731

Date: July 7, 2005

PABST PATENT GROUP LLP
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(404) 879-2160 (Facsimile)

JUL 15 2005

Produsts

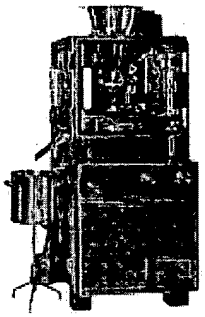
CLEANPRESS

The CLEANPRESS series was developed specifically for the pharmaceutical industry. From the design table to the compression room, these Kikusui presses are intended to meet with stringent GMP requirements and the demands of the modern tablet manufacturer.

At a time when compression machines are becoming more and more complex and difficult to operate, Kikusui has found a unique balance between necessary technology and user-friendliness. The Kikusui line is intended to run reliably whenever called upon, and provide years of trouble-free operation.

Kikusui's tableting machines will continue to progress hand-in-hand with the advancements of the pharmaceutical industry. By being the front-runner of the tableting industry Kikusui's CLEANPRESS machines will provide an answer to all of your compression needs.

- VIRGO



Small but Versatile !

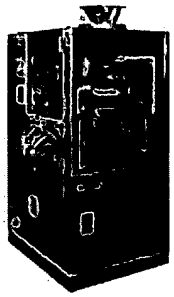
Its compact design takes up the least amount of floor space, yet the VIRGO has the power to perform all the necessary functions required in general tableting runs. With the instrumentation provided by Kikusui, the user can monitor forces for pre and main compression, as well as ejection force.

VIRGO SPECIFICATION		
Model	506	512
Number of stations	6	12
Type of tooling	IPT-B	IPT-B
Maximum pressure (t)	Pre 3 / Main 5	Pre 3 / Main 5
Maximum tablet dia. (mm)	16	16
Turret speed (r.p.m)	10 - 70	10 - 70
Tablets per hour	3,600 - 25,200	7,200 - 50,400
Filling depth (mm)	1 - 12.5 or 4 - 16	1 - 12.5 or 4 - 16
Tablet thickness (mm)	0 - 5	0 - 5
Main motor (kW)	2.2	2.2
Dimentions(WxDxH (mm))	750 x 630 x 1,610	750 x 630 x 1,610
Weight	1,100	1,100

VIRGO SPECIFICATION			
Model	519	524	2L512
Number of stations	19	24	12
Type of tooling	IPT-B	IPT-BB	IPT-B
Maximum pressure (t)	Pre 3 / Main 5	Pre 3 / Main 5	Pre 3 / Main 5

Maximum tablet dia. (mm)	16	11	16
Turret speed (r.p.m)	10 - 70	10 - 70	5 - 15
Tablets per hour	11,400 - 79,800	14,400 - 100,800	3,600 - 10,800
Filling depth (mm)	1 - 12.5 or 4 - 16	1 - 12.5 or 4 - 16	1st 1 - 8 / 2nd 3 - 10
Tablet thickness (mm)	5 - 35	0 - 5	
Main motor (kW)	2.2	2.2	2.2
Dimentions(WxDxH (mm))	750 x 630 x 1,610	750 x 630 x 1,610	750 x 630 x 1,610
Weight	1,100	1,100	1,100

- LIBRA2

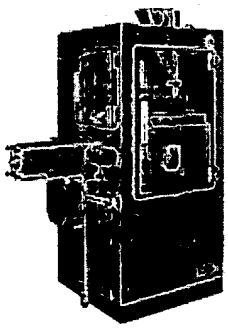


The Industry standard for reliability and simplicity!

The LIBRA has consistently shown an unmatched capacity for compressing difficult products. With its generous 8 ton pre-compression capability and wide speed range, the LIBRA has proven applicable to the various demands of the customers around the world.

LIBRA2 SPECIFICATION		
Model	836	845
Number of stations	36	45
Type of tooling	IPT-B	IPT-B
Maximum pressure (t)	Pre 8 / Main 8	Pre 8 / Main 8
Maximum tablet dia. (mm)	16	11
Turret speed (r.p.m)	10 - 100	10 - 100
Tablets per hour	21,600 - 216,000	27,000 - 270,000
Filling depth (mm)	1 - 12.5 or 4 - 16	1 - 12.5 or 4 - 16
Tablet thickness (mm)	0 - 5	0 - 5
Main motor(kW)	5.5	5.5
Dimentions(WxDxH (mm))	840 x 940 x 1,775	840 x 940 x 1,775
Weight	2,300	2,300

- HERCULES



Perfect for high compression needs!

The HERCULES is equipped with 5 ton pre and 15 ton main compression rollers which, along with its sturdy design, makes it the perfect machine for large and difficult-to-compress products.

HERCULES SPECIFICATION	

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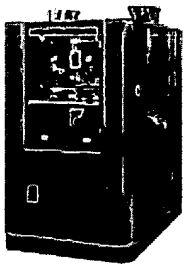
Model	1529
Number of stations	29
Type of tooling	IPT-D
Maximum pressure (t)	Pre 5 / Main 15
Maximum tablet dia. (mm)	25
Turret speed (r.p.m)	20 - 60
Tablets per hour	34,800 - 104,400
Filling depth(mm)	4 - 16
Tablet thickness (mm)	0 - 10
Main motor(kW)	3.7
Dimentions (WxDxH(mm))	800 x 900 x 1,760
Weight	2,500

- NEW GEMINI



The ultimate machine for large pharmaceutical runs!

Very compact for a machine of its output, the NEW GEMINI also has slide-track pressure rollers, quick-release fastening pins for changing parts, and the capability for one-sided discharge. The high-grade stainless-coated exterior and KANIGEN coated interior are both standard features.

NEW GEMINI SPECIFICATION			
Model	855	867	1545
Number of stations	55	67	45
Type of tooling	IPT-B	IPT-BB	IPT-D
Maximum pressure (t)	Pre 8 / Main 8	Pre 8 / Main 8	Pre 5 / Main 15
Maximum tablet dia. (mm)	16	11	25
Turret speed (r.p.m)	10 - 80	10 - 80	20 - 60
Tablets per hour	66,000 - 528,000	80,400 - 943,200	108,000 - 324,000
Filling depth (mm)	4 - 11 or 9 - 16	4 - 11 or 9 - 16	4 - 11 or 9 - 16
Tablet thickness (mm)	0 - 5	0 - 5	0 - 5
Main motor (kW)	7.5	7.5	7.5
Dimentions(WxDxH (mm))	1,160 x 1,200 x 1,915	1,160 x 1,200 x 1,915	1,200 x 1,200 x 1,935
Weight	3,900	3,900	5,000

NEW GEMINI SPECIFICATION		
Model	3L567	2L1545
Number of stations	67	45
Type of tooling	IPT-BB	IPT-D
Maximum pressure (t)	1st 3 / 2nd 3 / 3rd 5	Pre 5 / Main 15
Maximum tablet dia. (mm)	11	25

JUN 15 2005

Turret speed (r.p.m)	0 - 5	0 - 5
Tablets per hour	40,200 - 120,600	27,000 - 81,000
Filling depth (mm)	1st 1-5 / 2nd 1-5 / 3rd 1-5	1st 1-8 / 2nd 1-8
Tablet thickness (mm)	0 - 5	0 - 5
Main motor (kW)	7.5	7.5
Dimentions(WxDxH (mm))	1,160 x 1,200 x 1,830	1,200 x 1,200 x 1,935
Weight	3,600	5,000

- Libra-Virgo Dry Coat

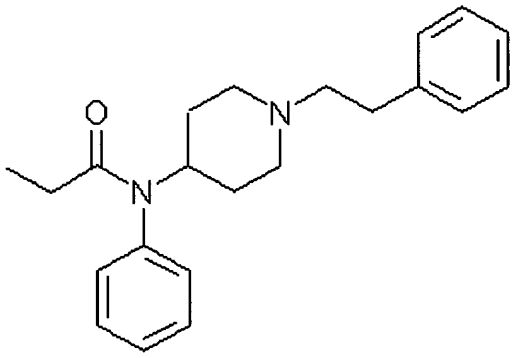
The definitive compression-coating tablet machine!
Of all compression-coating tablet machines, Kikusui's two models have the greatest number of detection devices for core presence. Both machines include easy-to-adjust core supply mechanism and easy-to-operate controls for additional benefits.

JUL 15 2005

Fentanyl

From Wikipedia, the free encyclopedia.

Fentanyl is an opioid analgesic, first synthesized in Belgium in the late 1950s, with an analgesic potency of about 80 times that of morphine. It was introduced into medical practice in the 1960s as an intravenous anesthetic under the trade name of Sublimaze. Fentanyl has an LD50 of 3.1 mg/kg. Fentanyl is a Schedule I drug under the Single Convention on Narcotic Drugs [1] (*http://www.incb.org/pdf/e/list/yellow.pdf*).



Contents

Analogues

The pharmaceutical industry has developed several analogues of fentanyl: -

1. alfentanil (Alfenta), an ultra-short (5-10 minutes) acting analgesic,
2. sufentanil (Sufenta), a potent analgesic (15 to 10 times more potent than fentanyl) for use in heart surgery.
3. remifentanil, currently the shortest acting opioid, has the benefit of rapid offset, even after prolonged infusions.
4. carfentanil (Wildnil) is an analogue of fentanyl with an analgesic potency 10,000 times that of morphine and is used in veterinary practice to immobilize certain large animals.

Therapeutic use

Today, fentanyls are extensively used for anesthesia and analgesia. Duragesic is a fentanyl transdermal patch used in chronic pain management. Actiq is a recently-developed solid formulation of fentanyl citrate on a stick that dissolves slowly in the mouth for transmucosal absorption. Actiq is intended for opiate-tolerant individuals and is effective in treating breakthrough cancer pain. The unit is a raspberry-flavored lozenge on a stick which is swabbed inside the mouth and gums to release the fentanyl quickly into the system; if the medication is swallowed, it is not effective, so as much of it must be placed on the mucosal surface as possible.

Fentanyl is frequently given intrathecally as part of spinal anesthesia or epidurally for epidural anesthesia and analgesia.

Illicit use

Illicit use of pharmaceutical fentanyls first appeared in the mid-1970s in the medical community and continues to be a problem in the United States. United States authorities classify fentanyl as a narcotic. To date, over 12 different analogues of fentanyl have been produced clandestinely and identified in the U.S. drug traffic. The biological effects of the fentanyls are indistinguishable from those of heroin, with the exception that the fentanyls may be hundreds of times more potent. Also, fentanyl has a shorter duration than heroin does. Fentanyls are most commonly used by intravenous administration, but like heroin, they may also be smoked or snorted. One common street name for fentanyl is *china white*.

Actiq has begun to appear on the streets under the street name of "percopop,", although the cost of the drug for actual patients is more than $30 USD for each unit, with the black market cost is at least ten times that.

Notoriety

In 1979, fentanyl was at the center of a major scandal in the sport of horse racing, as tests of urine samples revealed the presence of the drug in hundreds of thoroughbred race horses, most of which had raced at East Coast racetracks (in addition to its analgesic effects, fentanyl has a powerful stimulant effect on horses). The scandal resulted in the horses in question being disqualified from races in which they had either won or had earned a share of the purse, and the purse money was redistributed; some owners and trainers of the drugged horses were also fined and/or suspended.

The incapacitating agent used by Russian security forces in the October 2002 Moscow theatre siege incident was a fentanyl derivative, according to a statement issued by the Russian Health Minister Yuri Shevchenko.

External links

- Drug description (*http://cns.miis.edu/pubs/week/02110b.htm*), including suspected use in a variety of situations.
- US DOJ information: fentanyl (*http://www.usdoj.gov/dea/concern/fentanyl.html*)
- BBC news report (*http://news.bbc.co.uk/1/hi/world/europe/2377563.stm*)
- MPTP and drug-induced Parkinson's disease (*http://www.mydr.com.au/default.asp?Article=3299*)
- The Vaults of Erowid - MPTP (*http://www.erowid.org/chemicals/mptp/mptp.shtml*)

Analgesics

{Paracetamol (acetaminophen) } {Tetrahydrocannabinol} {Cannabinoids} {Ketamine}

NSAIDs

{Aspirin} {Celecoxib} {Diclofenac} {Ibuprofen} {Ketoprofen} {Ketorolac} {Naproxen} {Rofecoxib} {Indomethacin}

Opioids

{Alfentanil} {Buprenorphine} {Carfentanil} {Codeine} {Codeinone} {Dextropropoxyphene} {Dihydrocodeine} {Endorphin} {**Fentanyl**} {Heroin} {Hydrocodone} {Hydromorphone} {Methadone} {Morphine} {Morphinone} {Oxycodone} {Oxymorphone} {Pethidine} {Remifentanil} {Sufentanil} {Tramadol}

Retrieved from "http://en.wikipedia.org/wiki/Fentanyl"

Categories: Analgesics | Opioids | Phenylpiperidines

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Search results from the "OB_Rx" table for query on "019906."

Active Ingredient:	CLOMIPRAMINE HYDROCHLORIDE
Dosage Form;Route:	CAPSULE; ORAL
Proprietary Name:	ANAFRANIL
Applicant:	TYCO HLTHCARE
Strength:	25MG
Application Number:	019906
Product Number:	001
Approval Date:	Dec 29, 1989
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

Active Ingredient:	CLOMIPRAMINE HYDROCHLORIDE
Dosage Form;Route:	CAPSULE; ORAL
Proprietary Name:	ANAFRANIL
Applicant:	TYCO HLTHCARE
Strength:	50MG
Application Number:	019906
Product Number:	002
Approval Date:	Dec 29, 1989
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

Active Ingredient:	CLOMIPRAMINE HYDROCHLORIDE
Dosage Form;Route:	CAPSULE; ORAL
Proprietary Name:	ANAFRANIL
Applicant:	TYCO HLTHCARE
Strength:	75MG
Application Number:	019906
Product Number:	003
Approval Date:	Dec 29, 1989
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

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Division of Labeling and Program Support
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Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through May, 2005
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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,863,901

DATED : March 8, 2005

INVENTOR(S) : Jane Hirsh, Kamal Midha, Mark Hirsh, and Whe-Yong Lo

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 2, line 3, delete "clormipramine" and replace it with --clomipramine--.
Column 2, line 24, delete "powders" and replace it with --powder--.
Column 3, line 47, delete "Imanufacturing" and replace it with --manufacturing--.
Column 4, line 8, between "pharmaceutical" and "unit", delete "in".
Column 4, line 9, delete "is in the form".
Column 4, line 53, delete "compounds" and replace it with --compound--.
Column 9, line 22, delete "Kiusui" and replace it with --Kikusu--.
Column 12, line 65, delete "5".
Column 15, line 11, delete "CAT"; line 13, delete "Zolmitriptan (A)" and replace it with "Zolmitriptan CAT (A)".
Column 15, line 33, delete "releases" and replace it with --release--.
Column 15, line 37, delete "provide" and replace it with --provides--.
Column 16, line 38, delete "CTCC (A)" and replace it with --CAT (A)--.
Column 17, line 39, delete "CTCC " and replace it with --CAT--.
Column 18, line 36, delete "CTCC (C)" and replace it with --CAT (C)--.
Column 19, line 47, delete "CTCC" and replace it with --CAT--.
Column 20, line 48, delete "CTCC" and replace it with --CAT--.
Claim 1, column 21, line 53, delete "lease" and replace it with --least--.
Claim 15, column 23, line 24, delete "phentanyl" and replace it with --fentanyl-- .
Claim 19, column 23, line 12, delete "step" and replace it with --steps--.
Claim 20(a), column 24, line 21, delete "potion" and replace it with --portion--
Claim 20(a), column 24, line 29, delete "has".
Claim 20(b)(ii), column 24, line 42, delete "fit" and replace it with --first--;
Claim 20(b)(ii), column 24, line 46, delete "hereby" and replace it with --thereby--.
Claim 21, column 24, line 53 delete "indent" and replace it with --ingredient--.

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1201 Peachtree Street
Atlanta, GA 30361

PATENT NO. 6,863,901

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Patent No. 6,863,901
Dated: March 8, 2005

Pharmaceutical Composition for Compressed Annular Tablet with Molded Triturate Tablet for Both Intraoral and Oral Administration

CERTIFICATE OF CORRECTION

Certificate of Mailing under 37 CFR 1.8

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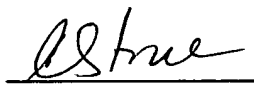
on July 7, 2005 .
Date



Signature

Carla Stone

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